REMARKS

Claims 36 to 53 are pending and claims 36-45, 47-49, 51-53 have been allowed. Claims 46 and 50 have been rejected on an anticipation argument in view of Ganem et al. U.S. No. 5,861,240. Claim 40 has been objected to.

In response, applicants amend claims 40 and 50, and provide arguments for why claim 46 and the amendments to claims 40 and 50 overcome the rejection and objection.

Reconsideration and allowance of the remaining claims are earnest requested.

The Objection to Claim 40

Claim 40 was objected to because this claim lacked a SEQ ID. A sequence ID has been added. Removal of the objection is solicited.

Rejection of Claims 46 and 50 under 35 U.S.C. § 102(e):

Claims 46 and 50 were rejected over a publication, U.S. No. 5,861,240 that describes the cloning of genomic DNA from BCBL-1 that has latent HHV-8 infections. However, the cloning reported in this reference did not involve a v-IL-6 like protein encoding gene. In fact, the reference explains that "the library of cloned fragments screened in FIG. 1 does not include the complete viral genome, raising the possibility that additional transcripts may be encoded by regions not yet cloned." (6th paragraph under example 4).

In fact, a v-IL-6 like protein gene is one of the missing genes in the figures. The publication emphasizes that only two viral genes and proteins were found, both of which differ from that of the present claimed invention. For example, the 3rd paragraph under Summary of the Invention states that only "[t]wo small transcripts were identified and

characterized, which transcripts represent the bulk of the virus-specific RNA transcribed from over 120 kb of the KSHV genome in infected cells. One is predicted to encode a small membrane protein; the other is an unusual polyadenylated RNA that accumulates in the nucleus to high copy number." Neither of these functions is consistent with that of the missing v-IL-6 like protein.

Furthermore, the only characterized sequence is clearly not the v-IL-6 sequence. The viral v-IL-6 product is described in the present application on the middle full paragraph of page 2 as a viral gene product v-IL-6 that "has conserved all 4 cysteine residues that are known to be involved in IL-6 disulfide bridging." In contrast, the only provided gene product (SEQ ID 2) in the cited reference is an approximately 60 aa long polypeptide that only has one cysteine residue, and lacks the important 4 cysteines.

Of course, an entire set of viral genes can and sometimes is expressed in an infection or even a cell culture, but which lacks isolated DNA. The reference acknowledges this fact with the statement that "[w]hen the phorbol ester TPA was added to the culture at 20 ng/ml, a dramatic inhibition of cellular growth was observed over the next 48 hours, with the appearance of considerable cytotoxicity. PolyA+ RNA was prepared from such cells and reverse-transcribed into radiolabeled cDNA as described above. When this probe was applied to the standard array of filter-bound restriction fragments of cloned HHV-8 DNA, virtually every HHV-8 fragment tested annealed to the probe, indicating widespread transcription of the viral genome." However, the expression of all genes within a lytic cycle, as described in this passage and as occurs in nature, requires all genes in a cell in vivo, and is different from expression of an isolated nucleic acid. Thus, claim 46, which recites "[a]n isolated nucleic acid molecule" and amended claim 50, which recites "recombinantly produced v-IL-6" differ both in recited structure and function. The reference does not describe either explicitly or inherently, any production of a v-IL-6 like molecule from an isolated nucleic acid molecule. Accordingly removal of the anticipation rejection against claims 46 and 50 respectfully is requested.

CONCLUSION:

In view of the foregoing, Applicants respectfully request the Examiner to withdraw the rejection against claims 46 and 50. The Examiner is invited to contact the undersigned attorney to resolve any issues, in order to expedite the prosecution of the application.

Respectfully submitted,

September 19, 2002
Date

Marvin A. Motsenbocker
Reg. No. 36,614

Customer ID No. 26633
HELLER EHRMAN WHITE & McAULIFFE
1666 K Street, NW, Suite 300
Washington, DC 20006-1228
(202) 912-2000 (telephone)

26633
PATENT TRADEMARK OFFICE

Copy of Marked Up Claims

36. Isolated viral interleukin-6 (v-IL-6) obtained by recombinant expression of the DNA of human herpes virus type 8 ("HHV-8") in an isolated cell.

37. An isolated polypeptide obtained by recombinant expression of the DNA of HHV-8 in an isolated cell, and which comprises the amino acid sequence of SED ID NO:2.

38. An isolated polypeptide having the amino acid sequence of SEQ ID NO:2.

39. A fragment of v-IL-6 that binds an interleukin-6 ("IL-6") receptor and comprises the amino acid sequence (residues 87-105 of SEQ ID NO:2) GFNETSCLKKLADGFFEFE.

40. A fragment as claimed in claim 39, which consists of the amino acid sequence (residues 87-105 of SEQ ID NO:2) GFNETSCLKKLADGFFEFE.

41. A fragment as claimed in claim 39, which binds to a human IL-6 receptor.

42. A fragment obtained from the human viral interleukin-6 (v-IL-6) of claim 36 that binds to the IL-6 receptor and which can competitively inhibit the biological activity of IL-6 in a suitable assay system wherein the fragment binds to the receptor.

43. An isolated nucleic acid molecule comprising the sequence SEQ ID NO:1 and that encodes v-IL-6.

44. An isolated nucleic acid as described in claim 43, consisting of the nucleotide sequence of SEQ ID NO: 1.

45. An isolated peptide having the amino acid sequence of SEQ ID NO:2 and obtained by recombinant expression of a DNA as described in claim 43 in an isolated cell.

46. An isolated nucleic acid molecule, hybridizing under stringent conditions to the nucleic acid as claimed in claim 44, encoding functional v-IL-6, wherein the nucleic acid encodes functional v-IL-6.

47. A test kit for the detection of v-IL-6 DNA or RNA, comprising a nucleic acid molecule consisting of the sequence of SEQ ID NO:1 as claimed in claim 43.

48. A composition comprising as an active ingredient the polypeptide as claimed in claim 37 and a pharmaceutically acceptable carrier.

49. A composition comprising as an active ingredient the nucleic acid as claimed in claim 43 and a pharmaceutically acceptable carrier.

50. A cell culture growth medium, comprising recombinantly produced v-IL-6 as claimed in claim [45] 46.

51. A fragment of a polypeptide that is obtainable by recombinant expression of the DNA of HHV-8 in an isolated cell and which comprises the amino acid sequence of SEQ ID NO:2.

52. A method of culturing cells in a medium using v-IL-6, comprising the step of adding v-IL-6 to the medium.

53. The method of claim 52, wherein the cells are selected from the group consisting of lymphocytes, hybridomas, hemopoietic cells and endothelial cells.